REMARKS

Applicants thank Examiner Joynes and Supervisory Examiner Kishore for courtesies extended during the Interview of February 19, 2003. Attached hereto is a copy of the chart used as a basis during the Interview of February 19, 2003 for a discussion regarding the present invention and the three references cited. As noted by the applicants during the interview but not reflected in the chart, LaHaye does teach the use of vitamin A **or** vitamin P (rutin) as possible non-essential ingredients for use in addition to or replacement of one or more "active ingredients".

Claims 3, 4 and 5 have been amended herein as suggested by the Examiner to more clearly define the present invention. The word "reverse" or "reversing" has been deleted from claims 3, 4 and 5 since it has not been shown that once vision has been lost through disease, that the loss can be reversed through use of the present invention to allow one to regain sight.

Enclosed herewith as suggested by the Examiner with appreciation, is a Declaration under 37 CFR 1.132 providing additional Age-Related Eye Disease Study (AREDS) results. The Declaration also incorporates by reference a copy of enclosed AREDS Report No. 8 titled *"A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation With Vitamins C and E, Beta Carotene, and Zinc for Age-Related Macular Degeneration and Vision Loss"* (hereinafter "AREDS Report") and two graphs taken from the AREDS Report illustrating the surprising beneficial effects of the present invention over the use of antioxidants – vitamins A, C and E alone or zinc and copper alone.

The subject invention has been proven useful in a ten-year, multicenter, prospective, Age-Related Eye Disease Study (AREDS) conducted by the

National Eye Institute (NEI) to strengthen and promote retinal health through the prevention, stabilization and/or treatment of visual acuity loss in people with particular ocular diseases. The results of AREDS, showed the present invention to have surprising beneficial effects over the use of either antioxidants or zinc/copper alone. The surprising beneficial effects of the present invention are most succinctly depicted in the two enclosed graphs taken from the AREDS Report, and are described in greater detail in the enclosed AREDS Report. Since the November 2001 NEI publication of the AREDS Report extolling the present invention's exceptional achievement in preserving vision, more than five (5) products sold by more than five companies have entered the nutritional market touting the "AREDS" formulation.

Claims 1-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek, U.S. Patent Number 6,103,756, (Gorsek) alone or in view of Newsome, D. A., et al., Oral Zinc in Macular Degeneration, Arch. Ophthalmol., Vol. 106, February 1988, pp. 192-198 (Newsome). Applicants respectfully traverse the subject rejection of claims 1-25 under 35 U.S.C. 103(a).

Gorsek teaches a formulation for treating macular degeneration comprising thirteen essential ingredients, i.e., vitamin C, vitamin E, vitamin A, magnesium, L-taurine, selenium, bilberry extract, lutein extract, lycopene extract, alpha lipoic acid, quercetin, rutin and citrus bioflavonoids, in addition to twenty-three non-essential ingredients, which include zinc and copper.

Newsome teaches that the administration of 5.3 times the RDA of zinc to treat macular degeneration in humans is **not** supported by study data.

The present invention as claimed comprises **6 to 10** times the RDA of vitamin A as beta carotene, **7 to 10** times the RDA of vitamin C, **13 to 18** times the RDA of vitamin E, **4 to 7** times the RDA of zinc and approximately the RDA of

copper. Gorsek teaches away from the subject invention. Gorsek teaches a formulation comprising thirteen essential ingredients including **0.2 to 4** (preferably 3.5) times the %DV of vitamin A as natural carotenoids, **1.5 to 100** (preferably 16.7) times the %DV of vitamin C, **3.3 to 67** (preferably 17) times the %DV of vitamin E, as well as twenty-three non-essential ingredients, which include **1.6** times the %DV of zinc and **0.5** times the %DV of copper. Gorsek does not teach or suggest the present invention or the surprising beneficial effects achieved by the specific formulation of vitamins A, C, E, zinc and copper of the present invention. Rather, Gorsek teaches that zinc and copper are non-essential ingredients. The present invention when compared to the teachings and suggestions of Gorsek differs in the **amount and type of vitamin A**, the **amount of zinc**, the **amount of copper**, and is considered by the National Eye Institute to provide an exceptional achievement in the preservation of vision. For these reasons, the claimed invention is not obvious in view of the teachings and suggestions of Gorsek.

The same is also true if the teachings of Newsome were to be combined with the teachings of Gorsek. Newsome teaches that the administration of 5.3 times the RDA of zinc for macular degeneration is **not** supported by study data. Therefor, Newsome teaches away from the use of high levels of zinc. If one were to combine, *arguendo*, the teachings of Gorsek and Newsome (there is no reason or incentive provided in either reference to do so, as is required) the present invention still differs in the **amount and type of vitamin A**, the **amount of zinc** (since Newsome teaches 5.3 times RDA of zinc is **not** supported) and the **amount of copper,** in addition to providing surprising beneficial effects considered by experts to provide an exceptional achievement (25% reduction in

vision loss) in the preservation of vision. Because the present invention differs significantly from the teachings and suggestions of Gorsek and Newsome, whether considered individually or in combination, the rejection of claims 1-25 under 35 U.S.C. 103(a) is inappropriate. Withdrawal of the rejection of claims 1-25 under 35 U.S.C. 103(a) over Gorsek or Gorsek in view of Newsome is thereby respectfully requested.

Claims 1-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LaHaye et al., U.S. Patent Number 5,075,116 (LaHaye) in view of Gorsek further in view of Newsome. Applicants respectfully traverse the subject rejection of claims 1-25 under 35 U.S.C. 103(a).

LaHaye teaches a formulation for treating macular degeneration having seven essential synergistic ingredients, i.e., vitamin C, vitamin E, zinc, copper, selenium, manganese and at least one of L-cysteine, pyridoxine or riboflavin, and as possible non-essential ingredients, vitamin A or vitamin P (rutin).

Gorsek teaches a formulation for treating macular degeneration comprising thirteen essential ingredients, i.e., vitamin C, vitamin E, vitamin A, magnesium, L-taurine, selenium, bilberry extract, lutein extract, lycopene, alpha lipoic acid, quercetin, rutin and citrus bioflavonoids, in addition to twenty-three non-essential ingredients, which include zinc and copper.

Newsome teaches that the administration of 5.3 times the RDA of zinc to treat macular degeneration in humans is **not** supported.

The present invention comprises **6 to 10** times the RDA of vitamin A, **7 to 10** times the RDA of vitamin C, **13 to 18** times the RDA of vitamin E, **4 to 7** times the RDA of zinc and approximately the RDA of copper. The present invention differs significantly from the teachings and suggestions of LaHaye. LaHaye teaches a formulation comprising seven essential synergistic ingredients, which

include **33.3** times the RDA of vitamin C, **2** times the RDA of vitamin E, **6.7** times the RDA of zinc and **2** times the RDA of copper. As taught by LaHaye, vitamin A or vitamin P could be used as a substitute for, or in addition to, one of the seven essential "active ingredients", but is not necessary. (Since no teachings are provided with regard to the amount of vitamin A or vitamin P that could optionally be used, the U.S. Food and Drug Administration's (FDA's) recommended daily allowance (RDA) as established by those skilled in the art of nutritionals, would be used.) The present invention as compared to the LaHaye composition differs in the **amount of vitamin C**, the **amount of vitamin E**, the **amount of copper**, the **amount of vitamin A** and provides surprising beneficial effects as illustrated in the two enclosed graphs titled *"Risk of Moderate to Severe Vision Loss"* and *"Risk of Developing Advanced AMD"* considered by experts in the field to provide an exceptional achievement (25% reduction in vision loss) in the preservation of vision.

The same is also true if the teachings of Gorsek were to be combined with the teachings of LaHaye. Gorsek teaches a formulation comprising thirteen essential ingredients including 0.2 to 4 (preferably 3.5) times the %DV of vitamin A, 1.5 to 100 (preferably 16.7) times the %DV of vitamin C, 3.3 to 67 (preferably 17) times the %DV of vitamin E, as well as twenty-three non-essential ingredients, which include 1.6 times the %DV of zinc and 0.5 times the %DV of copper. If one were to combine, *arguendo*, the teachings of LaHaye and Gorsek (there is no reason or incentive provided in either reference to do so, as is required) the present invention would still differ in the **amount of vitamin A** and the **amount of copper,** in addition to providing surprising beneficial effects.

The same is also be true if the teachings of Newsome were to be combined with the teachings of LaHaye and Gorsek. Newsome only teaches

that the administration of 5.3 times the RDA of zinc for macular degeneration is **not** supported by study data. If the teachings of Newsome were to be combined, *arguendo*, with the teachings of LaHaye and Gorsek (there is no reason or incentive provided in any of the references to do so, as is required) the present invention would still differ in the **amount of vitamin A** and the **amount of copper,** in addition to providing surprising beneficial effects considered by experts to provide an exceptional achievement (25% reduction in vision loss) in preserving vision. Because the present invention differs significantly from the teachings and suggestions of LaHaye, Gorsek and Newsome, whether considered individually or in combination, the rejection of claims 1-25 under 35 U.S.C. 103(a) is inappropriate. Withdrawal of the rejection of claims 1-25 under 35 U.S.C. 103(a) over LaHaye in view of Gorsek further in view of Newsome is respectfully requested.

Based on the above amendments and remarks, and the enclosed Declaration under 37 CFR 1.132 providing study results showing surprising, beneficial effects achieved with the present invention, claims 1-25 are believed to be patentable. Allowance of claims 1-25 is thereby respectfully requested.

Should there be any questions regarding this communication, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

Rita D. Vacca
Reg. No.: 33,624

Bausch & Lomb, Inc.
One Bausch & Lomb Place
Rochester, New York 14604-2701